

## REMARKS

The pending Office Action addresses and rejects claims 1-8, 10-14, 16-21, 23-27, and 29-33. Claims 29-31 were previously withdrawn from consideration. Reconsideration is respectfully requested in view of the above amendments and following remarks.

### ***Rejections Pursuant to 35 U.S.C. § 103***

The Examiner continues to reject claims 1-8, 10-14, 16-21, 23-27, and 32-33 pursuant to 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2002/0127265 of Bowman et al. ("Bowman") and International Patent Publication No. WO 01/85226 of Huckle et al. ("Huckle") as exemplified by Boland et. al. (*J. Macromol. Sci.-Pure Appl. Chem.*, 2001, A38(12), p 1231-1243) ("Boland"). Applicants respectfully disagree.

Independent claims 1 and 19 each recite, in part, that the scaffold includes a "nonwoven polymeric material having a density in the range of about 120 mg/cc to 360 mg/cc." In the Advisory Action, the Examiner argues that:

The amended limitation in claim 1 was already considered by the examiner. The claim amendment just adds duplicative verbiage. Independent claims 1 and 19 which recite that the claimed device "comprises" (i.e. open language) the generic dry laid nonwoven polymeric material do not prohibit the dry laid polymeric material from comprising a coating in order to achieve the recited density.

The Examiner is incorrect. Although independent claims 1 and 19 recite that the scaffold comprises a dry laid nonwoven polymeric material, the claims are also clear that the *nonwoven polymeric material* has a density in the range of about 120 mg/cc to 360 mg/cc. In other words, although the scaffold comprises a dry laid nonwoven polymeric material, the nonwoven polymeric material *itself* must have a density in the claimed range.

Neither Bowman nor Huckle, whether taken alone or in combination, teaches or suggests a nonwoven polymeric material that has the claimed density range. In the Office Action, the Examiner argues that "density limitations within the claimed range of 120 mg/cc...are taught by [Huckle] at page 21, line 34." This is incorrect. Huckle does not teach or suggest a nonwoven polymeric material that has the claimed density. In fact, the "needed

felt" disclosed by Huckle has "a density of 93 mg/cm<sup>3</sup>." Huckle at page 21, lines 14-15. Although Huckle later discloses a *scaffold* with "a density of 120 mg/cm<sup>3</sup>," the needled felt itself lacks the claimed density. Instead, the density of the scaffold made from the felt material is apparently increased by the addition of a PCL coating. Thus, Huckle plainly lacks the claimed nonwoven polymeric material having a density in the range of about 120 mg/cc to 360 mg/cc. As noted above, Applicants' claims require a nonwoven material having a certain density, i.e., the material itself has the claimed density, not the material plus a coating that increases the density. Huckle's nonwoven material, i.e., the needled felt, simply does not have a density in the claimed range. In fact, the claimed density is between 30% and 400% higher than the density of the needled felt disclosed by Huckle. Huckle therefore fails to teach or suggest a nonwoven polymeric material having a density in the range of about 120 mg/cc to 360 mg/cc.

Moreover, Huckle discloses that the PCL (polycaprolactone) is added as a reinforcing component to "fulfil a strengthening function and yet be rendered mouldable by a surgeon facilitating improved insertion of the scaffold into the defect." Huckle at page 14, lines 14-16. Thus, the properties of Huckle's nonwoven material are augmented by the addition of a coating with specific material properties, in particular, a melting temperature slightly above body temperature. *Id.* Although the coating imparts desirable material properties which are not present in the uncoated material, the difference in density between Huckle's uncoated and coated materials is merely a side effect. In contrast, Applicants claimed density range is specifically "designed to obtain mechanical characteristics ideal for augmenting meniscal repair." Published application at paragraph 0048, *see also* Examples 1-3.

Furthermore, in addition to fulfilling "a strengthening function," Huckle's coating presumably also results in a material that is moldable above body temperature and more rigid at body temperature, in contrast to the consistent properties of Applicants' material both before and after implantation. The PCL coating provided by Huckle therefore represents a different solution to differing problems than those addressed by Applicants claimed density range. Nevertheless, as discussed above, Huckle still fails to teach or suggest a nonwoven polymeric material that has the claimed density range.

Bowman also fails to teach or suggest a nonwoven material having a density in the claimed range. In fact, Bowman fails to provide any teaching or suggestion regarding the

density of a nonwoven material except for a "mesh material" that is disclosed as being a "low density, or open knitted mesh material." Bowman at paragraph 0066. Moreover, Bowman is directed to scaffold including foam reinforced with a mesh material that has an open structure so that the foam can penetrate the mesh. *See* Bowman at paragraph 10, FIG. 6. Thus, Bowman also fails to teach or suggest a nonwoven material having the claimed density range.

The combination of Bowman and Huckle therefore fails to teach or suggest Applicants' claimed invention. In particular, the combination of Bowman, which lacks any teaching of a density range, and Huckle, which discloses a density lower than the claimed range, fails to teach or suggest a scaffold including a nonwoven polymeric material having a density in the range of about 120 mg/cc to 360 mg/cc, as required by independent claims 1 and 19.

Accordingly, claims 1 and 19 distinguish over the combination of Bowman and Huckle and represent allowable subject matter. Claims 2-8, 10-14, 16-18, 20, 21, 23-27, and 32-33, which depend from claims 1 and 19, distinguish over the cited art at least because they depend from an allowable base claim.

#### ***Obviousness-Type Double Patenting Rejections***

The Examiner provisionally rejects claims 1-8, 10-14, 16-27, and 32-33 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-14, 17-29, and 32 of co-pending Application No. 11/427,477. The Examiner also provisionally rejects claims 1, 7, 10-14, 19, and 34-27 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1 and 8-11 of co-pending Application No. 11/856,743. The Examiner also provisionally rejects claims 1, 7, 8, 19, 24-27, 32, and 33 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 5, 7-9, 12, and 13 of co-pending Application No. 11/856,741.

Applicants believe that all pending claims are allowable. Applicants will file appropriate terminal disclaimers if so warranted. The instant application, however, was filed earlier than the applications that form the basis of the non-statutory double patenting rejections, and thus the Examiner should withdraw the provisional rejections and permit this application to issue as a patent without a terminal disclaimer (MPEP §804).

*Conclusion*

Applicants submit that all pending claims are allowable, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed necessary to expedite prosecution of this application.

Dated: August 12, 2009

Respectfully submitted,

By /George A. Xixis/  
George A. Xixis  
Registration No.: 38,664  
NUTTER MCCLENNEN & FISH LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, Massachusetts 02210-2604  
(617)439-3746  
(617) 310-9746 (FAX)  
Attorney for Applicants

1850615.1